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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/869,831 | 07/06/2001 | Haruyuki Matsunaga | 0020-4879P | 8981 |

2292 7590 05/16/2005

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,831

Applicant(s)

MATSUNAGA ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-26 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed March 4, 2005.

Amendments were made to the claims. Specifically, claims 1-8 were cancelled, and new claims 9-26 were added.

Claims 9-26 are pending in the instant application. Claim 26 is withdrawn as being drawn to an invention non-elected with traverse (see below). Claims 9-25 are under consideration in the instant application. Any rejection of record in the previous Office Action, mailed September 7, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Election/Restrictions

Applicant continues their traversal on the ground(s) that the invention is linked by a single general inventive concept, and disagrees with the Office's determination on the patentability of the claims (see for example pages 12-13 of Applicant's response). This is not found persuasive because the claims alleged to represent a single inventive concept over the prior art remain rejected, and thus cannot contain a special technical feature as required by the standards of Unity of Invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by amendment of the claims.**

The instantly amended claims recite the language “protein having an activity that can be quantitatively assayed” in sections (a) and (b) of claims 9 and 21, from which all other pending claims depend. Applicant points to the original claims, page 10 (lines 19-25), page 12 (lines 23-27) and page 16 (lines 4-20) of the specification for support for the new claims, and therefore for the limitation indicated above. However, the phrase “protein having an activity that can be quantitatively assayed” fails to find literal support at any of those locations. Furthermore, the Office can find no support for this limitation elsewhere in the instant specification. As such, the claims comprise a limitation that introduces New Matter, and therefore are rejected as such.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradfield (US Patent 5,650,283 as recited in the previous Office Action; henceforth Bradfield '283) in view of Moore (US Patent 5,846,711 as recited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action, and is now applied to newly added claims 9-25.**

Specifically, the newly added claims differ from the previous claims only in the recitation of the term "protein having an activity that can be quantitatively assayed" in reference to the reporter gene. It is submitted that there is no disclosure in the Bradfield '283 or Moore references indicating that their reporter genes (or selectable markers, interpreted as representing reporter genes in the original rejection) cannot be quantitatively assayed; therefore, those reporter genes (and selectable markers, interpreted as representing reporter genes) are considered capable of being quantitatively assayed, absent evidence to the contrary. Thus, the combined references continue to teach the claimed invention as amended.

Claims 9-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradfield (US Patent 6,432,692 as recited in the previous Office Action; henceforth Bradfield '692) in view of Moore (US Patent 5,846,711 as recited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action, and is now applied to newly added claims 9-25.**

Specifically, the newly added claims differ from the previous claims only in the recitation of the term "protein having an activity that can be quantitatively assayed" in reference to the

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reporter gene. It is submitted that there is no disclosure in the Bradfield '692 or Moore references indicating that their reporter genes (or selectable markers, interpreted as representing reporter genes in the original rejection) cannot be quantitatively assayed; therefore, those reporter genes (and selectable markers, interpreted as representing reporter genes) are considered capable of being quantitatively assayed, absent evidence to the contrary. Thus, the combined references continue to teach the claimed invention as amended.

Response to Arguments Concerning Claim Rejections - 35 USC § 103

Applicant's arguments filed March 4, 2005 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal regarding both rejections under 35 USC 103(a) set forth above:

1. Applicant asserts that the Office's interpretation of "selectable markers" as "reporter genes" is not reasonable. The alleged support for Applicant's assertion can be found at column 7, lines 39-45 of the Bradfield '692 reference; here, Applicant contends that the existence of separate definitions for the terms "reporter genes" and "selectable markers" necessitates that Bradfield considered these to be separate entities. Thus, Applicant contends that the Bradfield references fail to teach the elements as claimed (see for example page 16, first full paragraph of Applicant's remarks).
2. Applicant further asserts that the claims as amended require that the reporter genes recited retain the ability to be assayed in a quantitative manner. Applicant asserts that this concept is absent from the Bradfield reference (see for example page 16, second full paragraph of Applicant's remarks).

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3. Applicant asserts that the secondary reference in each rejection (Moore) fails to remedy the deficiencies of the Bradfield references, and therefore cannot remedy the deficiency in the rejection.

Applicant's arguments are not considered persuasive for the following reasons:

1. It is first noted that Applicant provides no definition set forth in the Bradfield '283 reference suggesting that "reporter genes" and "selectable markers" are separate entities. Thus, at least for the rejection comprising the Bradfield '283 reference, the suggestion that "reporter genes" and "selectable markers" are distinct and non-inclusive is moot.

Secondly, Bradfield '692 defines "reporter gene" as "a gene that encodes a product that is easily detectable by standard methods, either directly or indirectly," and "selectable marker" as "a gene encoding a product that, when expressed, confers a selectable phenotype." By definition, a phenotype represents "observable physical or biochemical characteristics" (i.e., something that must be detected). Thus, a "selectable marker" is a gene that encodes a protein that confers an observable (i.e., detectable) characteristic. Therefore, even in the context of the definitions set forth in Bradfield '692, a "selectable marker" is a *species* of "reporter gene," and is not distinct from reporter genes, as Applicant suggests.

Finally, it is noted that, even if Bradfield were to define "selectable marker" and "reporter gene" distinctly (which they clearly do not), it is the definition set forth in the instant specification (i.e., whether or not Applicant were to consider "selectable marker" and a "reporter gene" separate entities) that is relevant to the interpretation of the claims. However, no such distinction is made in the instant specification, prompting the broad interpretation of "reporter

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genes” to include “selectable markers,” which is clearly a reasonable interpretation in view of the definitions set forth in the Bradfield ‘692 reference as discussed above.

As such, Applicant’s argument is not considered persuasive, and the rejection is maintained and applied to the newly added/amended claims.

2. It is first noted that there is no support in the instant specification for the phrase “protein having an activity that can be quantitatively assayed” (see rejections under 35 USC § 112, first paragraph). Thus, there is no clear definition of what markers can or cannot be quantitatively assayed. As such, the Office can only interpret that any protein/marker/reporter can be assayed in a quantitative manner. This includes the “reporter genes” and “selectable markers” set forth in the Bradfield references cited in the rejection under 35 USC § 103 (a). Thus, it is asserted that, absent evidence that the reporter genes and/or selectable markers cannot be measured quantitatively, the Bradfield references continue to teach this limitation of the newly added/amended claims.

As such, Applicant’s argument is not considered persuasive, and the rejection is maintained and applied to the newly added/amended claims.

3. It is asserted by the Office that, given the analysis set forth above in sections (1) and (2) of the response to Applicant’s traversal, there is no deficiency in the Bradfield references concerning the nature of the reporter genes. Thus, there is no need for Moore to rectify such an alleged deficiency, and that argument is moot. Furthermore, it is noted that no other traversal is made concerning the combination of the Bradfield and Moore references, thus the combination of references is considered valid.

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As such, Applicant's argument is not considered persuasive, and the rejection is maintained and applied to the newly added/amended claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 11-13 of copending Application No. 09/550,173. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '173 application are species of the instant claims, and therefore make the instant claims obvious. **This rejection is maintained for the reasons set forth in the previous Office Action, and is now applied to newly added claims 9-25.**

Specifically, the newly added claims differ from the previous claims only in the recitation of the term "protein having an activity that can be quantitatively assayed" in reference to the reporter gene. It is submitted that the reporter genes disclosed in the claims of the '173 application can be quantitatively assayed, absent evidence to the contrary. Thus, the claims of

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the '173 application continue to be species of the instant claims, and therefore anticipate (and necessarily make obvious) the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments Concerning Double Patenting

It is noted that Applicant provides no traversal of the previously outstanding Double Patenting rejection. As such, no response to a traversal is deemed necessary, and the previous Double Patenting rejection is presumed valid.

Allowable Subject Matter

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER